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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

GILPIN, CRYSTAL M

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,971

Applicant(s)

BLAKE ET AL. *Cr*

Examiner

Crystal M Gilpin

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-221 is/are pending in the application.
- 4a) Of the above claim(s) 2-38, 40-74, 89 and 105-221 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 74-81, 83, 86, 87, 89-96, 98, 101, 102 and 104 is/are rejected.
- 7) ☒ Claim(s) 82, 84, 85, 88, 97, 99, 100 and 103 is/are objected to.
- 8) ☒ Claim(s) 1-221 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 and 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-74, 220 and 221, drawn to an intraocular lens, classified in class 623, subclass 6.46.
- II. Claims 105-129 and 148-219, drawn to haptics for an intraocular lens, classified in class 623, subclass 6.43.
- III. Claim 75-104 and 130-147, drawn to a method of introducing an intraocular lens in an eye, classified in class 606, subclass 107.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of inventions I and II could be inserted in the eye using a specific instrument, such as forceps, or the haptic arms could be positioned in the eye by manipulating it in ways other than flexing.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the

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subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the haptic of Invention I does not require aligned arms with the maximum interior angle of less than 90 or the flexibility in the arms. The subcombination has separate utility such as supporting a lens that is not implanted intraocularly (i.e. contact lens) or for reshaping the cornea.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Invention I- Species I: Claims 1-38, 220 and 221

Species II: Claims 39-74

Invention II- Species I: Claims 105-129

Species II: Claims 148-171

Species III: Claims 172-195

Species IV: Claims 196-219

Invention III- Species I: Claims 1, 39 and 75-104

Species II: Claims 130-147

If Invention I, II or III is chosen, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention..

During a telephone conversation with Jennifer Hayes on 13 March 2003 a provisional election was made without traverse to prosecute Invention III, Species I, claims 1, 39 and 75-104. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2-38, 40-74, 89 and 105-221 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Objections

Claims 82, 84, 85, 88, 97, 99, 100 and 103 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelman (USPN 4,268,921).

Regarding claim 1, Kelman discloses of an intraocular lens that has an optic (Figure 1, Ref. #12) and a haptic comprising at least one V-shaped element, formed by the pair of legs or haptics 18 and 20 in Figure 1, which have rounded ends and comprise two contact points.

Kelman further discloses an attachment for the optic to the haptic (Figure 1, Ref. # 34).

Regarding claim 75, Kelman discloses a method for introducing an intraocular lens into a small incision in the eye as separate pieces and attaching them within the eye (Column 2, Lines 24-36).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 39, 87, 90, 92, 93 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,268,921) in view of Simcoe (GB 2,171,912).

Regarding claim 39, Kelman teaches of an intraocular lens that has a separate optic (Figure 1, Ref. #12) and an attachment for the optic to the haptic (Figure 1, Ref. # 34). Kelman lacks the teaching of a haptic with at least two “V” shaped elements. Simcoe teaches of an intraocular lens with at least two “V” shaped elements (Figure 10, Ref. # 32, 32A and 32 B) that

allow for optimal flexibility during insertion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kelman to have at least two "V" shaped elements to provide optimal flexibility of the implant.

Regarding claims 92 and 93, Kelman discloses of a method of introducing an intraocular lens such that the lens component or optic is introduced prior to the support member or haptic (Column 3, Lines 59-64) to minimize the incision necessary to accommodate the intraocular lens (Column 5, lines 20-30).

Kelman does not expressly disclose that the haptic is introduced.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to insert the haptic prior to the optic because Applicant has not disclosed that inserting the haptic prior to the optic provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the haptic inserted prior to the optic because the incision required for insertion would still be minimal.

Therefore, it would have been an obvious matter of design choice to modify Kelman to obtain the invention as specified in claim 93.

Regarding claims 87 and 102, Kelman discloses an intraocular lens but lacks the teaching of a stretchable attachment of the haptic to the optic. Simcoe teaches of an intraocular lens with haptics or support members that are formed of hinged portions made of highly flexible or stretchable material so that they can adapt to the movements of the eye (Column 1, Lines 33-37 and Lines 55-58). Therefore, it would have been obvious to one of ordinary skill in the art at the

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time the invention was made to modify the invention of Kelman to have an intraocular lens with haptics that have a stretchable attachment so that the lens can adapt to the movements of the eye.

3. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,268,921) in view of Kelman (USPN 4,451,938).

Regarding claim 76, Kelman ('921) discloses a method for inserting an intraocular lens but lacks the teaching of bending the legs of the lens towards one another for insertion. Kelman ('938) teaches of a method for introducing a multi-component intraocular lens that includes bending the legs of the prosthesis towards one another to create smaller dimensions for easy implantation (Column 3, lines 20-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kelman ('921) to include bending the legs of the prosthesis towards one another so that the prosthesis would have smaller dimensions and allow for easy implantation.

4. Claims 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,368,921).

Regarding claims 77 and 78, Kelman discloses of a method of introducing an intraocular lens such that the lens component or optic is introduced prior to the support member or haptic (Column 3, Lines 59-64) to minimize the incision necessary to accommodate the intraocular lens (Column 5, lines 20-30).

Kelman does not expressly disclose that the haptic is introduced.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to insert the haptic prior to the optic because Applicant has not disclosed that inserting the haptic prior to the optic provides an advantage, is

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used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the haptic inserted prior to the optic because the incision required for insertion would still be minimal.

Therefore, it would have been an obvious matter of design choice to modify Kelman to obtain the invention as specified in claim 78.

5. Claim 79 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,268,921) in view of Koziol (USPN 4,878,910).

Regarding claim 79 Kelman discloses a method of inserting an intraocular lens but lacks the teaching of removing the optic of the lens and/or replacing it. Koziol teaches of a method of inserting an intraocular lens where the optic can be inserted or removed from its housing (Column 4, Lines 29-31 and Column 4, Lines 54-63) to replace a faulty or damaged lens. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kelman to allow the optic to be removed and replaced to allow for the focusing of the implant to be corrected.

Regarding claim 86, Kelman discloses an intraocular lens but lacks the teaching that the optic is made of a lower modulus material or more flexible material. Koziol teaches of a "soft" intraocular lens (Column 4, lines 12-19) that is made of a material that has a lower elastic modulus than the haptics or support (Column 3, Lines 15-25) to avoid sagging and distortion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kelman to make the haptics of the intraocular lens of a material of higher modulus than the optic to minimize sagging and distortion of the lens.

6. Claims 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,268,921) in view of Koziol (USPN 4,878,910) in further view of Anello et al. (USPN 5,984,962).

Regarding claims 80 and 81, Kelman discloses a method for inserting an intraocular lens and Koziol further teaches of removing and replacing the optic, however they both lack the teaching of repositioning the optic within the eye. Anello et al. teaches of an intraocular lens that is rotationally adjustable post-operatively for the correction of astigmatism (Column 5, line 65-Column 6, Line 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kelman to have an intraocular lens that can be repositioned for the correction of astigmatism.

7. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,268,921) in view of Patel (USPN 5,366,502).

Regarding claim 83, Kelman discloses of an intraocular lens but lacks the teaching of adding a second optic to the implant. Patel teaches of an intraocular lens with a supplementary lens for correction of changes that may occur after the healing of the first implantation (Column 6, Lines 20-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kelman to include a second optic to be implanted for correction of any defects with the first optic.

8. Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,268,921) in view of Simcoe (GB 2,171,912) and in further view of Kelman (USPN 4,451,938).

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Regarding claim 91, Kelman ('921) discloses a method for inserting an intraocular lens but lacks the teaching of bending the legs of the lens towards one another for insertion. Kelman ('938) teaches of a method for introducing a multi-component intraocular lens that includes bending the legs of the prosthesis towards one another to create smaller dimensions for easy implantation (Column 3, Lines 20-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kelman ('921) to include bending the legs of the prosthesis towards one another so that the prosthesis would have smaller dimensions and allow for easy implantation.

9. Claims 94 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,268,921) in view of Simcoe (GB 2,171,912) and in further view of Koziol (USPN 4,878,910).

Regarding claim 94 Kelman discloses a method of inserting an intraocular lens but lacks the teaching of removing the optic of the lens and/or replacing it. Koziol teaches of a method of inserting an intraocular lens where the optic can be inserted or removed from its housing (Column 4, Lines 29-31 and Column 4, Lines 54-63) to replace a faulty lens. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kelman to allow the optic to be removed and replaced to allow for the focusing of the implant to be corrected.

Regarding claim 101, Kelman discloses an intraocular lens but lacks the teaching that the optic is made of a lower modulus, or more flexible, material. Koziol teaches of a "soft" intraocular lens (Column 4, lines 12-19) that is made of a material that has a lower elastic modulus than the haptics or support (Column 3, Lines 15-25) to avoid sagging and distortion.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kelman to make the haptics of the intraocular lens of a material of higher modulus than the optic to minimize sagging and distortion of the lens.

10. Claims 95 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,268,921) in view of Simcoe (GB 2,171,912), in further view of Koziol (USPN 4,878,910) and in further view of Anello et al. (USPN 5,984,962).

Regarding claims 95 and 96, Kelman discloses a method for inserting an intraocular lens and Koziol further teaches of removing and replacing the optic, however they both lack the teaching of repositioning the optic within the eye. Anello et al. teaches of an intraocular lens that is rotationally adjustable post-operatively for the correction of astigmatism (Column 5, line 65-Column 6, Line 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kelman to have an intraocular lens that can be repositioned for the correction of astigmatism.

11. Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,268,921) in view of Simcoe (GB 2,171,912) and in further view of Patel (USPN 5,366,502).

Regarding claim 98, Kelman discloses of an intraocular lens but lacks the teaching of adding a second optic to the implant. Patel teaches of an intraocular lens with a supplementary lens for correction of changes that may occur after the healing of the first implantation (Column 6, Lines 20-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kelman to include a second optic to be implanted for correction of any defects with the first optic.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Parekh (USPN 5,141,507)


Blake (USPN 6,425,917).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 9:00-5:00 (Second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The group fax phone number for the organization where this application or proceeding is assigned are 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg
March 31, 2003


Paul B. Prebille
Primary Examiner